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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,350	12/18/2001	Michael N. Pollak	28758.57	4785

7590 03/28/2006

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1643

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/025,350

Applicant(s)

POLLAK ET AL.

Examiner

Anne L. Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed 12/12/2005 is acknowledged. Claims 21-27 are pending and examined on the merits.

#### ***Claim Rejections Maintained:***

#### ***Claim Rejections - 35 USC § 112***

2. Claims 21-27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of predicting a doubling of risk for prostate cancer for every 100 ng/ml increase in IGF-I levels, does not reasonably provide enablement for the full scope of the claimed methods, wherein any concentration above a reference level is deemed to indicate an increased risk for prostate cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments have been carefully considered but fail to persuade. Applicants assert that because the data in the specification demonstrate a significant linear relationship between the risk of prostate cancer and IGF-I levels, that one of skill in the art would not be required to engage in undue experimentation to practice the invention as claimed. Applicants state that the references cited in the previous Office action concern studies of the relationship between IGF-I measurements in patients already diagnosed with prostate cancer, and that any uncertainty in the art is not applicable to the claimed invention, because the data in the specification shows a reference level from patients that do not have prostate cancer. The

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argument that the data in the specification demonstrates a linear trend and therefore, it would not require undue experimentation to determine an appropriate reference level and to use any increase in IGF-I level as an indication of an increased risk for prostate cancer, is not found persuasive. While the data in the specification concerns a reference level of IGF-I of patients that never developed prostate cancer, the claimed methods are not so limited. In the claimed methods the reference level is established from a group of healthy individuals without prostate cancer. However, among some of these individuals, there may be some individuals who will go on to develop prostate cancer. Therefore, the claimed methods are broader in scope than the method presented in the specification and include methods such as those discussed in the cited art. With regard to the argument that demonstration of a linear trend in the data enables the claimed inventions that are broadly drawn to predicting increased risk using any reference level and using any amount above a reference level, this is not found persuasive for the reasons stated in the previous Office action, that a demonstration of linear trend is evidence of a relationship between IGF-I levels of prostate cancer, but does not provide one with knowledge of appropriate cut-off levels for baseline IGF-I levels.

3. Claims 21-27 remain rejected under 35 U.S.C. 102(a) as being anticipated by Mantzoros (Mantzoros et al, British Journal of Cancer 76(9): 1115-1118, 1997) for the reasons of record.

Applicants' arguments have been considered, but fail to persuade. Applicants continue to assert that because the specification teaches a prospective study to determine the association between IGF-I levels and prostate cancer incidence, whereas Mantzoros teaches data derived from patients already diagnosed with prostate cancer, that Mantzoros fails to teach the claimed

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methods. This is not found persuasive, because the claims are not drawn to methods determining whether an association exists between the IGF-I levels and prostate cancer incidence, but are drawn to methods determining risk in an individual. Mantzoros performs the steps of the claimed methods and also teaches statistic that may be used to interpret a blood test result. Therefore, Mantzoros teaches methods that are the same as that claimed.

The prior rejection is repeated below:

Mantzouros teaches a method of predicting risk of prostate cancer where concentrations of IGF-I are measured in healthy individuals and where IGF-I concentrations are measured in test individuals (happen to have either prostate cancer or BPH), and where a risk of prostate cancer is determined by comparing IGF-I levels to a reference. Mantzouros is able to determine that an increase in 60 ng/ml leads to a 91 percent increase in risk of prostate cancer. Thus, Mantzouros teaches methods that are the same as that claimed.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
March 21, 2006



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER